

REMARKS/ARGUMENTS

Claims 1-5 are pending in this application. Applicants have amended claims 1, 2 and 3 to correct for minor grammatical errors. Applicants respectfully request reconsideration of the above-referenced application in view of the following remarks.

1. The Examiner has objected to the specification as not containing an abstract of the disclosure as required by 37 C.F.R. 1.72(b). Attached hereto, on a separate sheet, is an abstract of the disclosure.

2. Claims 1 and 4-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ratsimamanga et al. U.S. Patent No. 3,366,669.

The Examiner asserted that Ratsimamanga discloses salts of asiatic acids with organic bases to produce water soluble, wound healing derivatives of asiatic acid where the organic bases differ as adjacent homologs to those of the instant claims. The Examiner then stated that the claimed invention would have been obvious to the skilled artisan because close structural similarity of the reference compound suggests the claimed compound. See Office Action at page 3.

Applicants respectfully disagree with the Examiner's ground for rejection.

Ratsimamanga teaches salts of asiatic acids with organic bases (i.e., hemisuccinates, salts of hemisuccinates and salts with alkylaminoalkanols or dialkylaminoalkanols) to simply produce water soluble derivatives of asiatic acid. See col. 1, lines 30-31 and Example 4. Ratsimamanga does not disclose any therapeutic effect of the salts nor does Ratsimamanga compare the efficacy of the salts with that of the derivative acid.

The present invention, however, claims salts of asiatic and madecassic acids with selected organic bases that exhibit unexpected effects and properties relative to the salts of the Ratsimamanga reference. The salts of the present invention are formulated with select organic bases to allow for an optimum modulation of the hydrophilic-lipophylic balance. Ratsimamanga, however, discloses salts which are formulated to simply allow for water soluble derivatives of the acid. The salts of the claimed invention are dramatically more effective than the derivative acid in therapeutic use. In addition, the claimed salts are absorbed to a greater extent when compared to the acid derivative. As illustrated in Example 7, the claimed salts are surprisingly substantially more effective than the acid in delaying cicatrization and reducing inflammation. Ratsimamanga, however, does not teach or disclose that the salt compounds are therapeutically more effective than the asiatic acid. As such, the hemisuccinates, salts of hemisuccinates and salts with alkylaminoalkanols or dialkylaminoalkanols, disclosed in the Ratsimamanga reference, do not teach or suggest the claimed compound. The salts of the claimed invention clearly demonstrate unexpected pharmacological effects and unobvious improved properties.

The unexpected improved efficacy of the claimed salts with respect to the derivative acids highlights the inventive merits of the claimed compounds and the process capable of obtaining them. For these reasons, the salts claimed in claim 1, and depending claims 4-5, and their surprising potency over asiatic and madecassic acids could not, at all, be derived from Ratsimamanga.

With respect to claim 5, Applicants respectfully assert that the ratio of base to acid ensures an adequate formulation and absorption of the compound by maintaining an adequate hydrophilic-lipophylic balance. Thus, it does not simply as stated by the Examiner

ensure complete formation of the salt form and, as such, would not have been obvious to one skilled in the art.

Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection of claims 1 and 4-5 under §103(a).

3. Claims 2-3 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ratsimamanga et al. U.S. Patent No. 3,366,669, in view of Mason, Jr. et al. U.S. Patent 4,393,048. Applicants respectfully disagree with the Examiner's ground for rejection.

Applicants respectfully submit that claims 2 and 3 are not obvious over Ratsimamanga in view of Mason. The combination does not teach or suggest salts of asiatic and madecassic acids with select bases that when treated with water at a ratio between salt and water ranging from 1:12 to 1:20, are able to easily form a hydrophylic gel, as claimed by the Applicants. In fact, Mason discloses a water-soluble hydrogel formed by an alkali metal alginate and glycerin capable to form in suitable conditions a dried film-coating flexible, stretchable, transparent, protective, non-toxic and adherent on the wound surface. Mason does not teach or suggest formulating a salt compound of an acid by formulating the acid with select bases which facilitate the formation of a hydrophylic gel.

Since neither Ratsimamanga nor Mason discloses individually or in combination the salt compounds recited in claims 2 and 3, Applicants' claimed invention clearly would not have been obvious over the references of record.

Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection of claims 2-3 under §103(a).

CONCLUSION


For these reasons, it is believed that all of the claims as presented, are patentable, and that this application is in allowable condition.

The Commissioner is hereby authorized to charge any additional fees which may be required for the timely consideration of this amendment under 37 C.F.R. §§ 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-4500, Order No. 0558-4018.

Respectfully submitted,
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